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Innocoll
Pharmaceuticals

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510(k) Summary

1. **Date Prepared:** August 15, 2005

2. **Submitter**

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Tel: +353 (0) 9064 86834
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Submission Correspondent:

Aaron Wyse
Director of Quality and Regulatory Affairs

3. **Proprietary Name:** CollaGUARD™

4. **Common Name:** Topical Wound Dressing

5. **Device Classification:** Product Code: KMF
Classification Name: Dressing Wound Collagen
Regulatory Class: Unclassified

6. **Statement of Substantial Equivalence:**

CollaGUARD™ is substantially equivalent in materials of construction and intended use to Collagen Topical Wound Dressing (K040558) manufactured by Collagen Matrix Inc.

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7. Intended Use

CollaGUARD may be used for the management of wounds such as:

- Pressure ulcers
- Venous stasis ulcers
- Diabetic ulcers
- First and second degree burns
- Partial and full thickness wounds
- Superficial injuries

8. Description

CollaGUARD™ is a clear collagen matrix film intended for topical use. The product is supplied sterile for single use only.

9. Biocompatibility

CollaGUARD's biocompatibility testing has been completed against the requirements of ISO 10993 -1:2003. CollaGUARD has passed the requirements of all tests and has been shown to be a biocompatible topical wound dressing.

10. Conclusion

CollaGUARD™ is a member of a family of collagen products distributed by Innocoll Pharmaceuticals. The collagen products have an extensive and established history of safety and effectiveness. Collagen has a primary role in all phases of wound healing making it an effective agent for managing wound treatment.

CollaGUARD™ is substantially equivalent to the predicate device delineated in this submission and meets the requirements for premarket notification as defined in CFR21, Part 807.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Innocoll Pharmaceuticals
% Mr. Aaron Wyse
Director of Quality and Regulatory Affairs
IDA Business and Technology Park,
Garrycastle, Athlone
Co. Westmeath, Ireland

OCT - 2 2006

Re: K061746
Trade/Device Name: CollaGuard
Regulation Name: Collagen Dressing
Regulatory Class: Unclassified
Product Code: KGN
Dated: August 15, 2006
Received: August 31, 2006

Dear Mr. Wyse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

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510(k) Number (if known): K061746

Device Name: CollaGUARD

Indications For Use:

Indications:
CollaGUARD may be used for the management of wounds such as:

- Pressure ulcers
- Venous stasis ulcers
- Diabetic ulcers
- First and second degree burns
- Partial and full thickness wounds
- Superficial injuries

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061746